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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			FERNANDEZ, SUSAN EMILY	
			ART UNIT	PAPER NUMBER
			1651	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/609,401	Applicant(s) SATO ET AL.	
	Examiner Susan E. Fernandez	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 7-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 7-19 is/are rejected.
- 7) ☒ Claim(s) 13 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2-8-06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed February 3, 2006, has been received and entered.

Claims 1, 3-5, and 7-19 are pending and examined on the merits.

Claim Objections

Claims 13 and 17 are objected to because of the following informalities: Claim 13 recites "claim1" which should be replaced with "claim 1" in order to include a space after "claim." Claim 17 recites "triglyceriede" which is the misspelling of the term "triglyceride." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 9, 11, and 13-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 15, and 16 are rendered indefinite by the recitation "the moisture content of the enzyme" recited at line 8 of claim 1 and line 1 of claims 15 and 16. It is unclear how the enzyme comprises of water, therefore it is unclear it has a moisture content. It appears that the "enzyme" referred to in this recitation is the immobilized enzyme composition. Also, it is unclear whether the moisture content is the moisture content before, during, or after dehydrating the immobilized

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enzyme. Thus, claims 1, 5, 9, 11, 13, 15, 16 and 18 are rejected under 35 U.S.C. 112, second paragraph.

Claims 13 and 14 are indefinite since “an amount of enzyme” does not appear to limit the quantity of enzyme. It is suggested that the recitation be replaced with “the amount of enzyme.” Furthermore, the claims are rendered indefinite by the unclear recitation “based on the weigh to said carrier.” It is suggested that the recitation be replaced with “based on the weight of said carrier.”

Claims 15 and 16 are rendered indefinite by the recitation “the moisture content of the enzyme.” It is unclear how the enzyme comprises of water, therefore it is unclear it has a moisture content. It appears that the “enzyme” referred to in this recitation is the immobilized enzyme composition.

Claim 15 is rendered indefinite by the recitation “after contacting.” It is unclear what “contacting” is being referred to since the claim does not state what was contacted with the enzyme. It is unclear that the “contacting” refers to step (ii) of claim 1. Additionally, the claim is indefinite since it recites a moisture content which is “from 15 to 50% by weight.” It is unclear what the weight is based on (e.g. carrier, total immobilized enzyme weight, total reaction mixture weight).

Claim 16 is rendered indefinite by the recitation “after contacting.” It is unclear what “contacting” is being referred to since the claim does not state what was contacted with the enzyme. It is unclear that the “contacting” refers to step (ii) of claim 3. Additionally, the claim is indefinite since it recites a moisture content which is “from 1 to 30% by weight.” It is unclear

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what the weight is based on (e.g. carrier, total immobilized enzyme weight, total reaction mixture weight).

Claim 17 is indefinite since it recites an amount "from 100 to 1,000% by weight." It is unclear what the weight is based on. It appears that the amount should be read as one which is from 100 to 1,000% by weight based on the weight of the carrier.

Claims 18 and 19 are indefinite since "a moisture content of said immobilized enzyme" does not appear to limit the moisture content of the immobilized enzyme. It is suggested that "a moisture content" be replaced with "the moisture content." Additionally, claims 18 and 19 are indefinite since they recite a moisture content which is "120 to 200 wt. %" First, it is unclear whether "wt." is an abbreviation of "weight." Clarification is required. Furthermore, it is unclear what the weight is based on (e.g. carrier, total immobilized enzyme weight, total reaction mixture weight). Finally, it is unclear how a "moisture content" can be over 100% if the moisture content is based on the total weight of the immobilized enzyme.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 4, 7, 8, 10, 12, 14, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bosley et al. (US 5,658,769) in light of Macrae et al. (EP 322,213) and in view of Ikuta et al. (US 5,569,594).

In Example I, Bosley et al. teaches treating oleic acid and an alcohol with an immobilized lipase which results in the esterification of both oleic acid (as pointed out in column 3, lines 19-25) and the alcohol (abstract). Specifically, Bosley et al. discloses mixing 171.55 g oleic acid with other ingredients and 25 g immobilized lipase (column 3, lines 42-45). Even if the carrier is 50 to 99% of the weight of immobilized lipase, the fatty acid (oleic acid) contacting the immobilized lipase would be in the amount of about 700% to 1300% by weight based on the weight of the carrier. Thus, the limitations of step ii) of claim 3 are met by the reference.

The reaction mixture obtained is maintained at a particular temperature for 117 hours, wherein "approximately every 24 hours a vacuum was applied to the mixture...to remove water by codistillation with tertiary butanol" (column 3, lines 47-52). Thus, prior to the first application of vacuum (dehydrating under reduced pressure as required by instant claim 7), the fatty acid (oleic acid) is in contact with the immobilized enzyme without drying.

Bosley et al. also discloses particularly preferred immobilization methods for obtaining the immobilized lipase used for practicing the disclosed methods. These preferred methods

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include the methods of Macrae et al. (EP 322213). See column 2, lines 43-45. In one example, Macrae et al. discloses preparation of immobilized lipase by combining 8 grams of a carrier (EP 100) with 10.0 grams of a lipase powder (page 5, lines 14-21). For this example, if all the lipase powder is absorbed on the carrier, the amount of the enzyme is 125% based on the weight of the carrier, thus meeting the limitations recited in claim 14 under examination. Furthermore, given the amounts of carrier and lipase powder disclosed in the Macrae reference and assuming all the lipase powder is immobilized on the carrier, the amount of carrier in the immobilized lipase is 44% of the total weight.

It is noted that Bosley et al. does not expressly state the moisture content of the immobilized enzyme based on the weight on the carrier during, before, or after the dehydration by vacuum steps. However, Bosley et al. specifies that in enzymes which require water, the amount of water present in the immobilized enzyme is "...at most 5% by weight based on the total initial reaction mixture" (column 3, lines 15-19), which teaches the limitation recited in instant claim 16. See also claim 1. Thus, in the Bosley example, the amount of water sought through the codistillation process for water removal is about 12 g (5% of (171.55g + 45.0g + 4.3g + 25g)). As indicated above, the amount of carrier in the immobilized lipase is 44% of the total weight. Thus, the moisture content of the immobilized enzyme of Bosley et al. is 109% based on the weight of the carrier ($12\text{g water} / (0.44 * 25\text{ g carrier}) * 100$).

Furthermore, the reference teaches the limitation of instant claim 8 since the presence of the immobilized enzyme at any stage could be considered the storing of the immobilized enzyme. Also, in addition to application of a vacuum, water removal may be accomplished by using molecular sieves (column 3, lines 7-10), thus teaching the limitations of claim 7.

Bosley et al. and Macrae et al. differ from the claims in that they do not teach that the moisture content of the immobilized enzyme is 1% to 50% by weight based on the weight of the carrier. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have ensured that the moisture content of the immobilized enzyme after contacting with fat/oil is an amount that falls in a low range, such as the range of 5% to 50% by weight based on the weight of the carrier. One of ordinary skill in the art would have been motivated to do this Bosley et al. requires periodic drying of the reaction mixture to remove water and indicates that "the reaction in the process according to the present invention is driven by water removal from the system..." (column 3, lines 7-8). Moreover, Bosley et al. does not provide any lower limits as to the moisture content of the reaction mixture. Clearly the selection of the extent of water removal would have been an obvious matter of optimization on the part of the artisan of ordinary skill. Through routine optimization, the artisan of ordinary skill in the art would have dried the immobilized enzyme at varying degrees, arriving at various moisture contents including those recited in the claims.

Bosley et al. and Macrae et al. also do not expressly disclose treating the carrier in advance with a fat-soluble fatty acid or a derivative thereof before adsorption with the lipase.

Ikuta et al. discloses the preparation of an immobilized lipase for transesterification involving a fat and/or fatty acid (abstract). Ikuta et al. indicates that "...it may be more preferable that the immobilized lipase...is prepared by bring the polymer matrix into contact with an enzyme solution containing lipase...in the presence of fatty acids or derivatives thereof. For example, **the polymer carrier is pretreated with a fatty acid or its derivative** and then

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brought into contact with an aqueous lipase solution...so as to immobilize the lipase ...onto the polymer carrier” (column 5, line 59 through column 6, line 1, emphasis added).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have modified the preparation of the immobilized lipases used in the Bosley invention such that the carrier is pretreated with a fatty acid or its derivative prior to lipase immobilization. One of ordinary skill in the art would have been motivated to do this since it would have resulted in an immobilized lipase suitable for esterification of fatty acids and derivatives thereof as required for practicing the Bosley invention. Furthermore, one would have been motivated to do this since Ikuta et al. teaches the pretreatment as a preferable step in preparing immobilized lipases.

It is noted that the claims now recite bringing the immobilized enzyme into contact with a composition “consisting essentially of” at least one of a fatty acid, fatty acid triglyceride, fatty acid partial glyceride, or mixtures thereof. It is also noted that the composition which is contacted with the immobilized enzyme contains ingredients in addition to the fatty acid ingredients recited in applicant’s claims. MPEP § 2111.03 clearly states that “[t]he transitional phrase ‘consisting essentially of’ limits the scope of a claim to the specified materials or steps ‘and those that do not materially affect the basic and novel characteristic(s)’ of the claimed invention.” (Citations omitted, emphasis in original.) Moreover, MPEP § 2111.03 states that claims recited in “consisting essentially of” language should be construed as if recited in open “comprising” language, absent some evidence that the additional ingredients in the prior art process/product materially affect the basic and novel properties of the claimed invention:

For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims

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of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See, e.g., PPG [Industries v. Guardian Industries], 156 F.3d at 1355, 48 USPQ2d at 1355 (“PPG could have defined the scope of the phrase ‘consisting essentially of’ for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.”). See also *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963).

On the current record there is no evidence that any of the additional ingredients present in the prior art composition would affect the basic and novel properties of the prior art method such that the prior art method is truly different than the claimed method. Thus, applicant’s claims must be construed as if reciting “comprising” language, thereby encompassing the additional ingredients in the prior art composition, despite the “consisting essentially of” language. A holding of anticipation is therefore required.

Lastly, note specifically that MPEP 2111.03 further provides that “[w]hen an applicant contends that additional steps or materials in the prior art are excluded by the recitation of ‘consisting essentially of,’ applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention.” (Citations omitted.)

Thus, a holding of obviousness is clearly required.

Claims 1, 5, 9, 11, 13, 15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1,008,647 in view of Shimizu et al. (U.S. Pat. No. 6,258,575) and Ruthven (Encyclopedia of Separation Technology, Vol. 2, John Wiley & Sons, Inc., 1997, page 1072).

EP '647 discloses preparation of an immobilized enzyme for esterification where the enzyme is immobilized on anion exchange resin without drying. The immobilized enzyme is treated with fat and/or oil which are the reaction substrates. See claims 1, 4, 6, and 7 on pages 7 and 8. Example 1 describes the immobilization of 10 g of lipase on 10 g of anion exchange resin, followed by treatment with 40 g of soybean oil (page 5, lines 26, 34, and 37). Thus, the limitations of instant claims 5, 9, and 13 (amount of enzyme is 100 wt. % based on the weight of the carrier) are taught. Soybean oil serves as a mixture of fatty acid triglyceride or fatty acid partial glyceride. In Example 1, the quantity of this oil is 400% by weight based on the weight of the carrier.

Finally, the moisture content of the immobilized enzyme in the '647 invention is given as having a water content of "20% **or more** by weight" (page 4, lines 35-37, emphasis added), thus satisfying the moisture content limitations indicated in instant claims 15 and 18.

Additionally, it is noted that the reference also teaches the treatment of the carrier with a fat-soluble fatty acid or a derivative thereof before the immobilization step (page 2, paragraph [0012]). Thus, the limitations of instant claim 11 are taught by the reference.

EP '647 does not expressly disclose that the immobilized enzyme is contacted with fatty triglyceride, etc. in the amount of 800 to 5,000% by weight based on the weight of the carrier.

However, Shimizu '575 discloses that 2000 g of soybean-squeezed oil is passed through a column holding 20 g of immobilized lipase. See Example 2, column 8, lines 25-36. The oil mixture is sent through the column multiple times (column 8, line 36 through column 9, line 7, in particular column 8, lines 59-62). The weight of the carrier, an anion exchange resin, may be estimated by performing a calculation using the dimensions of the column (column 8, lines 28-

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30) and the density range of exchange resin provided by Ruthven (page 1072, first paragraph under "Density and Specific Gravity"). A density of 700 g/L was used for the estimation, and the mass of resin was determined to be about 48 g. Therefore, the amount of soybean-squeezed oil used in Shimizu '575 was about 4100% by weight based on the weight of the carrier. This fits within the range recited in part (ii) of claim 1.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have increased the amount of fatty acid triglyceride, fatty acid partial glyceride, or mixtures thereof used for treating the immobilized enzyme as described in EP '647.

One of ordinary skill in the art would have been motivated to do this because it would have improved exposure of the immobilized enzyme to the reaction substrate. Furthermore, the selection of the appropriate amount of fat used to treat immobilized enzyme clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that the result or effect of the process would differ depending on the amount of fat employed. The artisan of ordinary skill in the art would have recognized the suitability in using the same ratios of oil to carrier as discussed in Shimizu '575 in performing the methods of EP '647, since both function in the same manner (for esterification).

EP '647 also does not expressly disclose that the moisture content of the enzyme is 5% to 50% or 15% to 50% by weight based on the weight of the carrier, after contacting the immobilized enzyme with fatty acid triglyceride, fatty acid partial glyceride, or mixtures thereof.

Additionally, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have ensured that the moisture content of the immobilized enzyme

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after contacting with fat/oil is an amount that falls within the range of 5% to 50% or 15% to 50% by weight based on the weight of the carrier.

One of ordinary skill in the art would have been motivated to do this because '647 states that "after the lipolytic enzyme is immobilized by adsorption onto a carrier for immobilization, the initial esterification reaction is conducted by directly bringing the immobilized enzyme **without drying** into contact with the substrate, and removal of this excess water content in this initial esterification requires extra reaction time but can be effected in a considerably shorter time than the time for conventionally conducted drying of the immobilized enzyme" (page 5, lines 3-7, emphasis added). Since reduction of water content is desired, one of ordinary skill in the art would have been motivated to have ensured that the water content is 20% or more by weight, or 40 to 60% by weight, since this was the preferred water content range for the embodiment wherein the drying step proceeds enzyme immobilization (page 4, paragraph [0037]). It would have been applicable to any immobilized enzyme used for decomposing oil and fat, even when no active drying step is included in the process of treating immobilized enzyme. Moreover, the selection of the appropriate water content clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that the result or effect of the immobilized enzyme on fat/oil decomposition would differ depending on the water content of the treated immobilized enzyme. A holding of obviousness is clearly required.

Claims 1, 5, 9, 11, 13, 15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,716,610 or U.S. 2003/0096383.

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In the response filed on May 27, 2005, applicants note that EP 1,008,647, U.S. 6,716,610, and U.S. 2003/0096383 share common identification of inventors as well as priority claims to Japanese 10-346822 and 10-350920 and the disclosures therein are considered to be equivalent. See discussion above about EP '647.

The '610 patent and '383 application do not expressly disclose that the fatty triglyceride, etc. is 800 to 5,000% by weight based on the weight of the carrier. Furthermore, the references do not expressly disclose that the moisture content of the enzyme is 5% to 50% or 15% to 50% by weight based on the weight of the carrier, after contacting the immobilized enzyme with fatty acid triglyceride, fatty acid partial glyceride, or mixtures thereof.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have varied the amount of fatty acid triglyceride, etc. used in the '610 patent or '383 application.

One of ordinary skill in the art would have been motivated to do this since, as stated above, the selection of the appropriate amount of fat used to treat immobilized enzyme clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill. Although Example 3 in each of the references discloses the treatment of immobilized enzyme with a fatty acid (aliphatic acid) in the amount of 1000% by weight based on the weight of the carrier, one of ordinary skill in the art would have expected that this amount would have been suitable when the substrate is a fatty triglyceride, a fatty acid partial glyceride or mixtures thereof, instead of a fatty acid. Note that '610 points out that the substrate includes aliphatic acids (column 5, line 6), and that "for preparation of esters having a single aliphatic acid component, partial glycerides and/or triglycerides, these aliphatic acids can be used alone or may

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be used as a mixture of two or more type thereof" (column 5, lines 10-14). Thus, the aliphatic acids of Example 3 can be substituted with partial glycerides and triglycerides. Finally, the references do not disclose any upper limits for the amounts of fat/oil used to treat immobilized enzyme. Therefore, the reference does not suggest that the amount of fat/oil can not be in the weight range recited in claim 1.

Additionally, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have ensured that the moisture content of the immobilized enzyme after contacting with fat/oil is reduced to an amount that falls within the range of 5% to 50% or 15% to 50% by weight based on the weight of the carrier.

One of ordinary skill in the art would have been motivated to do this because '647 (essentially the same disclosure as '610 and '383) discloses that "after the lipolytic enzyme is immobilized by adsorption onto a carrier for immobilization, the initial esterification reaction is conducted by directly bringing the immobilized enzyme **without drying** into contact with the substrate, and removal of this excess water content in this initial esterification requires extra reaction time but can be effected in a considerably shorter time than the time for conventionally conducted drying of the immobilized enzyme" (page 5, lines 3-7, emphasis added). Since reduction of water content is desired, one of ordinary skill in the art would have been motivated to have ensured that the water content is 20% or more by weight, or 40 to 60% by weight, since this was the preferred water content range for the embodiment wherein the drying step proceeds enzyme immobilization (page 4, paragraph [0037]). It would have been applicable to any immobilized enzyme used for decomposing oil and fat, even when no active drying step is included in the process of treating immobilized enzyme. Moreover, the selection of the

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appropriate water content clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that the result or effect of the immobilized enzyme on fat/oil decomposition would differ depending on the water content of the treated immobilized enzyme.

A holding of obviousness is clearly required.

Applicant's arguments filed February 3, 2006, have been fully considered but they are not persuasive. Applicant asserts that EP '647 and the other Shimizu references with equivalent disclosures (US 6,716,610, US 2003/0096383) do not teach contacting the immobilized enzyme with 800 to 5,000 wt.% of fatty acid triglyceride, fatty acid partial glyceride or mixtures thereof based on the weight of the carrier. Though the reference provides guidance for the treatment ratio of 400 wt.%, there is nothing in EP '647 or the other Shimizu references that limits the amount of fatty acid triglyceride, etc. to a certain ratio with respect to the carrier. Furthermore, as discussed above, the oil concentrations disclosed in Shimizu et al. (U.S. Pat. No. 6,258,575) demonstrate that large ratios of oil to carrier, such as those which fit within the ranges recited in the claims, would have been appropriate for contacting with immobilized lipase. Moreover, it is noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Though the applicant's declaration showed that the treatment ratio of 400% described in EP '647 yields a moisture content outside of the recited ranges, the applicant has not demonstrated that

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practicing EP `647 with treatment ratios within the recited ranges does not yield the recited moisture content ranges.

Since it would have been obvious to have practiced the EP`647 invention with the high ratios of oil recited in the claims, the moisture content of the immobilized enzyme after contacting the immobilized enzyme with fatty acid triglyceride/fatty acid partial glyceride would have resulted in the claimed range.

Thus, the rejections over 1, 5, 9, 11, 13, 15, and 18 over EP`647, the other Shimizu references, and the secondary references must be maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 9, and 13 are directed to an invention not patentably distinct from claims 1-4 of commonly assigned U.S. Pat. No. 6,716,610. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims recite the same basic steps as recited in the patented claims, to the extent that the limitations recited in the claims under examination are contained under the patented claims with the exception of the fat/carrier amount recited in claim 1, and the amount of enzyme recited in claim 13. While the weight ranges of enzyme, fatty acid, fatty acid triglyceride, etc. as recited in the claims had not been expressly recited in US '610, the selection of the appropriate amount of fat used to treat immobilized enzyme, and amount of enzyme immobilized on the carrier clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned claims, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting

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inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

In conclusion, claims 1, 5, 9, and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,716,610. The claims are directed to an invention not patentably distinct from U.S. '610.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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